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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.         |
|---|-------------|----------------------|---------------------|--------------------------|
| 09/920,137  | 08/01/2001  | George Heavner       | CEN0250             | 5801                     |
| 27777   | 7590        | 01/10/2006           |                     |                          |
| PHILIP S. JOHNSON<br>JOHNSON & JOHNSON<br>ONE JOHNSON & JOHNSON PLAZA<br>NEW BRUNSWICK, NJ 08933-7003 |             |                      | EXAMINER            | SEHARASEYON, JEGATHEESAN |
|   |             |                      | ART UNIT            | PAPER NUMBER             |
|   |             |                      | 1647                |                          |



DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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J&J PAT. DKT. SECTION



|                       |  |                  |
|-----------------------|--|------------------|
| Office Action Summary | Application No.                            | Applicant(s)     |
|                       | 09/920,137                                 | HEAVNER ET AL.   |
|                       | Examiner<br>Jegatheesan Seharaseyong, Ph.D | Art Unit<br>1647 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 October 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3, 9 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1-3, 9 and 16 is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: Amended claims.



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## DETAILED ACTION

1. This Office Action is in response to Applicants response and amendments filed 10/19/2005.  
Claims 1-3, 9 and 16 are pending and subject of this action.
2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

### *Specification*

3. The specification is objected to because of sequence non-compliance. Page 93 and 94, describe sequences, however, sequence listing does not provide for the various sequences (e.g: SEQ ID NO: 34 and 363). This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

### HOW TO SEND SEQUENCES TO USPTO

The addresses below are effective 5 June 2004. Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio (<<http://www.uspto.gov/ebc/efs/downloads/documents.htm>>, EFS Submission User Manual - ePAVE)
2. Mailed to:  
Mail Stop Sequence

Commissioner for Patents  
P.O. Box 22313-1450  
Alexandria, VA 22313-1450

3. Hand Carry, Federal Express, United Parcel Service or other delivery service to:  
U.S. Patent and Trademark Office  
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401 Dulaney Street  
Alexandria, VA 22314

4. Applicants are also required to amend the figure legends. See for example, figure 2 needs to be amended 2A-2B.

***Claim Rejections - 35 USC § 112***

5. The rejection of claims 1-3, 9 and 16 under 35 U.S.C. 112, second paragraph is withdrawn because of Applicants persuasive arguments and amendments.

6. The rejection of claims 1-3, 9 and 16 under 35 U.S.C. 112, first paragraph is withdrawn because of Applicants persuasive arguments and amendments.

7. Following a telephone interview with Guy Kevin Townsend on 1/3/06 the Examiner suggests that Applicants modify the following pending claims for clarity and readability. Applicants are requested to provide the changes along with the sequence listing.

**In the Claims**

Please amend claim 1, 9 and 16. as follows:

1 (amended). An isolated human anti-TNF antibody, comprising at least one variable region, wherein the variable region of the heavy chain comprises SEQ ID NO: 7 and the variable region of the light chain comprises SEQ ID NO: 8.

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9 (amended). A composition comprising an isolated human anti-TNF antibody, comprising at least one variable region, wherein the variable region of the heavy chain comprises SEQ ID NO: 7 and the variable region of the light chain comprises SEQ ID NO: 8, and at least one pharmaceutically acceptable carrier or diluent.

16 (amended). A medical device comprising an isolated human anti-TNF antibody, comprising at least one variable region, wherein the variable region of the heavy chain comprises SEQ ID NO: 7 and the variable region of the light chain comprises SEQ ID NO: 8, wherein said device is suitable for contacting or administering said anti-TNF antibody by at least one model selected from parenteral, subcutaneous, intramuscular, or intravenous.

8. Applicant is given ONE MONTH from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

9. Upon amending the claims they will be allowable.

### Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 1/06

  
ROBERT S. LANDSMAN, PH.D.  
PRIMARY EXAMINER